DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

LABTECH KFT.
Zsolt Katonai
Quality Manager
Vagu 4
Debrecen, 4031 HU

Re: K140847
Trade/Device Name: CARDIOSPY ECG Holter Systems
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, Ambulatory, With Analysis Algorithm
Regulatory Class: Class II
Product Code: MLO
Dated: October 20, 2014
Received: October 22, 2014

Dear Zsolt Katonai:

This letter corrects our substantially equivalent letter of December 5, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140847

Device Name
Cardiospy ECG Holter System

Indications for Use *(Describe)*
The Cardiospy ECG Holter System is intended for use in a clinical, by qualified professionals, for patients requiring ambulatory (Holter) monitoring 24, 48, 72, 168 h hours. Such monitoring is most frequently used for purpose of prospective and retrospective cardiac data and arrhythmia analysis.
The System, among others, provides the detection and reporting features appropriate to the indications below for children and adults of all ages (up to 2 years):
• Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia.
• Evaluation of patients for ST segment changes
• Evaluation of patients with pacemakers
• Reporting of time domain heart rate variability
• Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after MI. or cardiac surgery.)
• Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
• Clinical and epidemiological research studies

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

LABTECH	**510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)**	Vág utca 4. H-4031, Debrecen, Hungary Phone : +36-(52)-310-128 Fax : +36-(52)-412-023 E-mail : service@labtech.hu

(Cardiospy ECG Holter System) **Date: 4th December 2014**

510(k) Summary of Safety & Effectiveness

510(k) Number: K140847

Submitter

Labtech Kft.
Vág utca 4. H-4031, Debrecen, Hungary
Phone : +36-(52)-310-128
Fax : +36-(52)-412-023
E-mail : medical@labtech.hu

Responsible person and title : Mr. Dr. Béla Kincs – Managing Director

Contact person and title : Mr. Zsolt Katonai – Quality Manager

Device trade name: Cardiospy ECG Holter System

Common/Usual name: Ambulatory ECG Holter System

Classification name : Electrocardiograph, Ambulatory with analysis algorithm (per 21CFR section 870.2800)

Product code: MLO

Device class: II (according to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm)

Device models: EC-1H, EC-2H, EC-3H, EC-12H

Predicate devices

1. Vista Plus – Novacor France - K042108
2. Spiderview ELA MEDICAL Inc. - K032466
3. Cardio ID+(RZI153±) - ScottCare (ROZINN ELECTRONICS Inc.) - K022540
4. Digitrak Plus - BRAEMAR CORP - K993617

Device Description

The battery powered Cardiospy ECG Holter System provides 1, 2, 3 and 12 channel recordings, depending on the recorder and patient cable type being used.

The Cardiospy ECG Holter System includes a recorder, an USB dongle (for blue tooth communication) and the Cardiospy software. The Class II medical device is intended to acquire, record and store up to 24, 48, 72 hours and 1 week of ECG data of patients that have been connected to the recorder and are undergoing Holter monitoring and to support the medical staff in analyzing and deciding the proper and adequate diagnosis. The cardiac data and analysis provided by Cardiospy ECG Holter System will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

The universal analysis SW provides full disclosure ECG recordings on channels with a precise automatic QRS and PM detection, template and rhythm analysis, QRS classification, efficient ST, QT, AF, PM, HRV time and frequency based analysis with color coded display and printing with interactive modification possibilities in the automatic analysis in several languages. Export-available.

LABTECH

510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)

Vág utca 4. H-4031,
Debrecen, Hungary
Phone : +36-(52)-310-128
Fax : +36-(52)-412-023
E-mail : service@labtech.hu

The evaluation software works with a conventional PC- based computer under Win 2000/XP/VISTA , Windows 7, Windows 8 operating systems.
The connection between the Holter and computer is performed by using Bluetooth and USB dongle.
The Cardiospy analysis software provides ECG records of excellent quality.

Indications for use:
The Cardiospy ECG Holter System is intended for use in a clinical, by qualified professionals, for patients requiring ambulatory (Holter) monitoring 24, 48, 72, 168 h hours. Such monitoring is most frequently used for purpose of prospective and retrospective cardiac data and arrhythmia analysis.
The System, among others, provides the detection and reporting features appropriate to the indications below for children and adults of all ages (up to 2 years):

- Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia.
- Evaluation of patients for ST segment changes
- Evaluation of patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after MI. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies

Intended Use:
The ECG Holter System is intended for acquiring ambulatory ECG signals from patients. Patients are people with coronary problems or suspected coronary problems.
This ambulatory electrocardiograph, and associated analysis system, can be used on patients without limitation on patient age or gender.
The Holter Recorder procedure is one of the many tools that clinicians use to capture infrequent or activity provoked ECG rhythm abnormalities outside of the physician's office. Indications for conducting Holter recording are:

- Arrhythmias
- Chest pain
- Unexplained syncope
- Shortness of breath
- Palpitations
- Evaluation of a pacemaker
- Regulation of anti-arrhythmic drugs
- Evaluation of a patient after myocardial infarction
- Family history of heart disease

Non-clinical testing of the product and its accessory proves that the following standard requirements are met:

Table 1 – Fulfilled standard requirements

LABTECH

510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)

Vág utca 4. H-4031,
Debrecen, Hungary
Phone : +36-(52)-310-128
Fax : +36-(52)-412-023
E-mail : service@labtech.hu

Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard	FR Publication Date	Remarks
5-53	IEC	60601-1-2 Edition 3:2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	08/05/2013	Was tested and certified by TÜV Rheinland Intercert Kft.- Product Certification Body 1132 Budapest Váci út 48 A-B Hungary
5-85	IEC	60601-1-6 Edition 3.0 2010-01	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability	01/30/2014	
3-127	AAMI / ANSI / ISO	60601-2-47:2012,	medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)	07/09/2014	
3-118	AAMI / ANSI	EC57:2012	Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms. (Cardiovascular)	01/30/2014	
3-72	AAMI ANSI	EC53:1995/(R) 2008	ECG cables and leadwires	01/30/2014	
5-40	ISO	14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices	08/20/2012	
13-32	AAMI ANSI IEC	62304:2006	Medical device software - Software life cycle processes	08/20/2012	
5-73	ISO	15223-1 Second Edition 2012-07-01	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	01/15/2013	
2-181	AAMI ANSI ISO	14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice	03/16/2012	
Voluntary	IEC	60601-1:2005 (Third edition)	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance	12/01/2005	
Voluntary	IEC (EN)	61000-3-2:2005 (EQV) (61000 – 3-2:2006 +A1+A2)	Electromagnetic compatibility (EMC) — Part 3 – 2: Limits — Limits for harmonic current emissions (equipment input current ≤16 A per phase)	11/01/2006	Was tested and certified by TÜV Rheinland Intercert Kft.- Product Certification Body 1132 Budapest Váci út 48 A-B Hungary
Voluntary	IEC (EN)	61000-3-3:2008 (EQV) (61000-3-3:2008)	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection	06/01/2009	Was tested and certified by TÜV Rheinland Intercert Kft.- Product Certification Body 1132 Budapest Váci út 48 A-B Hungary
Voluntary	ISO	13485:2003(E)	Medical devices — Quality management systems — Requirements for regulatory purposes	07/15/2003	Extended according to 21 CFR Part 820 and CMDCAS requirements. QMS certificate issued by SGS United Kingdom Ltd.

LABTECH	**510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)**	Vág utca 4. H-4031, Debrecen, Hungary Phone : +36-(52)-310-128 Fax : +36-(52)-412-023 E-mail : service@labtech.hu

Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard	FR Publication Date	Remarks
Voluntary	Council Directive	93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	10/11/2007	Certificate issued by SGS United Kingdom Ltd

The test results prove that the device fulfills the standard requirements.

Comparison of technology characteristics to predicate devices

Table 2 – Comparison with predicate devices

Device	Vista Plus	Spiderview	Cardio Id+ (RZ153+)	Digitrak Plus	Cardiospy ECG Holter System
Manufacturer	Novacor	ELA Medical	Rozinn (ScottCare)	Braemar (delivered by ZYMED/PHILIPS)	Labtech Kft
510(k) FDA registration	**K042108**	**K032466**	**K022540**	**K993617**	**K140847**
Type	Digital	Digital	Digital	Digital	Digital
Number of channels	1, 2, 3	2, 3, 5, 9	2, 3, 12 (option)	2, 3	1, 2, 3, 12
Recording duration	Up to: 264 h	Up to: 96 h	Up to: 48 h	Up to: 120 h	24, 48, 72, 168 h
Recording rate	200 Hz	200 Hz	1024 Hz	175 Hz	128 Hz … 1024 Hz
Resolution	10 bit	15 bit	12 bit	10 bit	16 bit
Dynamic range	+/- 6 mV	+/- 16 mV	+/- 6 mV or +/- 3 mV or +/- 1,5 mV		+/- 20 mV
Pacemaker spike detection and reporting	Yes	Yes	Yes	Yes	Yes
Open lead detection	Yes	Yes	Yes	Yes	Yes
Impedance test	Yes	Yes	Yes	Yes	Yes
Storage capacity	Up to 512 MB	Up to 64 MB	Up to 512 MB		2GB
Memory type	CF card	MMC or SD flash card	CF card	Internal Flash memory (non removable)	microSD
LCD	Yes	Yes	Yes	Yes	Yes
Size	86x54x19 mm	97x54x23 mm	108x79x22 mm	85x65x20 mm	53x67.5x18.5 mm
Weight	100 g	110 g	145 g	100 g	50 g
Accessories	Belt, shoulder strap, pouch, neck pouch	Belt + pouch	Belt + pouch	Belt + pouch	Belt + pouch attachable to patient's belt + pouch attachable to patient's neck
Batteries	2 AAA 1,5 V	1 AA 1,5 V	2 AAA 1,5 V	1 AA 1,5 V	1x1.2 V AAA NiMH battery (or 1x1.5 V AAA alkaline battery)
Rechargeable batteries	Accepted	Accepted	Accepted	Accepted	Accepted

LABTECH

510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)

Vág utca 4. H-4031,
Debrecen, Hungary
Phone : +36-(52)-310-128
Fax : +36-(52)-412-023
E-mail : service@labtech.hu

Device	Vista Plus	Spiderview	Cardio Id+ (RZ153+)	Digitrak Plus	Cardiospy ECG Holter System
ECG display	At any time (programmable)	Preview only	Preview only	Preview only	Preview only
Real-type built in analysis	HR calculation	No	No	No	No
Event marker	Yes	Yes	Yes	Yes	Yes
Display during recording					
Time	Yes	Yes	Yes	Yes	Yes
HR	Programmable	No	No	No	No
HR curve	Programmable	No	No	No	No
Replay and analysis system	HolterSoft Ultima	Syneview/Synescope	Holter for Windows	Philips 1810 series or 2010 software	Cardiospy software
Software	HolterSoft Ultima	Synetec	2010 Plus Holter	Mars Unity	Cardiospy software
Software developer	Novacor	ELA Medical	AietMaq	Marquette	Labtech Kft
PC based	Yes	Yes	Yes	Yes	Yes
OS compatibility	Windows 98,NT,2000, XP	Windows 98,NT,2000, XP	Windows 98,NT,2000, XP	NA	Windows XP (Service Pack 2) Windows XP SP3, Vista, 7, 8 (32 and 64 bit)
Input data	Digital (CF card from Vista series recorders)	Digital (PCMCIA flashcards from Syneflad/MMC or SM cards from Spiderview) and tape	Digital (USB transfer from Zymed Digitrak Plus recorder)	Digital (USB transfer from the "Seer Light" interface) and tape	Digital (Bluetooth or USB transfer)
Graphic User Interface	Yes	Yes	Yes	Yes	Yes
Templates (shapes) edition	Yes	Yes	Yes	Yes	Yes
Events list display	Yes	Yes	Yes	Yes	Yes
Arrhythmia detection	Yes	Yes	Yes	Yes	Yes
Conduction abnormalities detection	Yes	Yes	Yes	Yes	Yes
ST segment	Multi channel	Multi channel	Multi channel	Multi channel	Multi channel
Superimposition	Yes	Yes	Yes	Yes	Yes
PM patient analysis	Yes	Yes	Yes	Yes	Yes
Report customization	Yes	Yes	Yes	Yes	Yes
Report edition	Yes	Yes	Yes	Yes	Yes
ECG strip edition and printing	Yes	Yes	Yes	Yes	Yes
Archiving	Yes	Yes	Yes	Yes	Yes
Report Export	Yes	No	No	No	Yes

LABTECH	**510(k) SUMMARY of SAFETY & EFFECTIVENESS (according to CFR 807.92)**	Vág utca 4. H-4031, Debrecen, Hungary Phone : +36-(52)-310-128 Fax : +36-(52)-412-023 E-mail : service@labtech.hu

Device	Vista Plus	Spiderview	Cardio Id+ (RZ153+)	Digitrak Plus	Cardiospy ECG Holter System
Afib	Yes	No	No	No	Yes
Events Histograms/trends	Yes	Yes	Yes		Yes
RR histogram	Yes	Yes	Yes	Yes	Yes
Editing/Printing full disclosure	Yes	Yes	Yes	Yes	Yes
Editing tools for QRS insertion/suppression	Yes	Yes	Yes		Yes
Time domain HRV	Yes	Yes	Yes	Yes	Yes
Frequency Domain	Yes	Yes	Yes	Yes	Yes
HRV	Yes	Yes	Yes	Yes	Yes
QT	Yes	Yes	Yes	Yes	Yes
Networking	Yes	Yes	Yes	Yes	Yes

Statement indicating the device is similar to the products of comparable type in commercial distribution

In conclusion the Holter ECG System can be declared **identical in intended use, indications for use to the predicate devices** listed and very **similar in functionality, design, material and performance to applicable standards**. The main modification is the implementation of the Bluetooth wireless technology.

The test results in this submission demonstrated that these small differences do not raise any new questions of safety and effectiveness to the subject device and the subject device is substantially equivalent to the predicate devices.

This information provides reasonable assurance that the Cardiospy ECG Holter System will perform in a safe and effective manner.

Dr. Béla Kincs
managing director